510(k) Summary

510(k) Number K103522

JAN 26 2011

1. **Submitter:**
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   Date Prepared: October 27, 2010
   Contact: Mª Luisa Gómez de Agüero, Quality and Regulatory Manager

2. **Identification of the Device:**
   Proprietary-Trade Name: Sedecal SPL-HF-4.0 (and SPL-HF-2.0)
   Classification Name: Mobile x-ray system, Product Code IZL
   Common/Usual Name: Mobile Diagnostic X-Ray System

3. **Equivalent legally marketed device**: K020436 Sedecal Models SP-HF-2.8 and SP-HF-4.0

4. **Description of the Device**: The Sedecal SPL-HF-4.0 portable x-ray generator consists of: X-ray Unit with: Control Panel with controls and displays for radiographic operations; Power Module containing control and power components; HV Tank that comprises the High Voltage Transformer, the Filament Transformer and the X-ray Tube; and a Collimator with controls to limit the X-ray beam; a Handswitch and a Mobile Column with an Articulated Arm and a Cassette Basket.

5. **Indications for Use (intended use)** Intended for use by a qualified/trained doctor or technician on both adult and pediatric subjects for taking diagnostic radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position. (Not for mammography)

6. **Technological Characteristics**: This device has the same technological characteristics (i.e., design, material, chemical composition, energy source) as the predicate device. Specifications are nearly identical. This submission represents an updated design of our previous model in K020436.

7. **Discussion of the nonclinical tests in the premarket notification submission for a determination of substantial equivalence:** We performed electrical safety (IEC 60601-1), electromagnetic compatibility testing, (IEC 60601-1-2), software validation testing, and testing to IEC 60601-1-3 and IEC 60601-2-7.

8. **Conclusion**. Based on the results of the nonclinical tests (that demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed devices) we conclude that this modified x-ray system is safe and effective as the predicate identified in paragraph (3). Furthermore, the materials and construction methods are nearly identical to the predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Sedecal SA
% Mr. Daniel Kamm, P.E.
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JAN 26 2011

Re: K103522
Trade/Device Name: Sedecal SPL-HF-4.0 (and SPL-HF-2.0)
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile x-ray system
Regulatory Class: II
Product Code: IZL
Dated: November 24, 2010
Received: December 1, 2010

Dear Mr. Kamm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S Pastel

Mary Pastel, ScD.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K103522

Device Name: Sedecal SPL-HF-4.0 (and SPL-HF-2.0)

Indications For Use:
This Portable Diagnostic Radiographic System is intended for use by a qualified/trained doctor or technician on both adult and pediatric subjects for taking diagnostic radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position. (Not for mammography)

Prescription Use X AND/OR Over-The-Counter Use ____.
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In-vitro Diagnostics (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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